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10/552,610	09/14/2006	Gillian Smith	03981/0203467-US0	6340
7278 7590 02/20/2009 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770				
EXAMINER				
PAK, YONG D				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,610

**Applicant(s)**

SMITH ET AL.

**Examiner**

YONG D. PAK

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 15, 16, 32-36, 38, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 1, 32-34 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 35, 36, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

This application is a 371 of PCT/GB04/01453.

The amendment filed on November 14, 2008, amending claims 35 and 36 and adding claims 40-41, has been entered.

Claims 1, 15-16, 32-36, 38, and 40-41 are pending. Claims 1, 32-34, and 38 are withdrawn. Claims 15-16, 35-36, and 40-41 are under consideration.

#### ***Response to Arguments***

Applicant's amendment and arguments filed on November 14, 2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied.

#### ***Drawings***

In view of the amendment of the specification, the objection of the drawings has been **withdrawn**.

#### ***Objections to the Specification***

In view of the amendment of the specification, the objection to the specification have been **withdrawn**.

***Claim Objections***

In view of the amendment of claims 35-36, the objection to claims 15-16 and 35-36 has been **withdrawn**.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Withdrawn Rejections**

In view of the amendment of claim 35 (deletion of the phrase "the treated first sample", the rejection of claim 35 and claims 15-16 depending therefrom and 43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn**.

In view of the amendment of claim 36 (replacing the phrase "an increase" with "a higher", the rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn**.

**Maintained Rejection**

Claim 35 and claims 15-16 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the phrase administering to the mammal "detecting effectiveness of a skin treatment". It is not clear to the Examiner as to how those skilled in the art can detect effectiveness of a skin treatment. This is because CYP2S1 levels of a treated first sample is compared to another sample, whose basal CYP2S1 levels may be higher or lower than the basal CYP2S1 of the untreated first sample. Further, if a sample is taken from a patient suffering from a skin condition not associated with an increase or decrease of CYP2S1 expression, the method yields a false negative. Therefore, the method lacks essential step(s).

Applicants argue that claim 35 is definite because claim 35 has been amended to clarify that the skin treatment is effective if CYP2S1 levels are modulated and samples for comparison are adjacent to each other (such that that basal levels of samples are presumed to be the same)". Examiner respectfully disagrees. It can not be "presumed" that the basal levels of CYP2S1 of samples adjacent to each other are the same. Basal CYP2S1 levels may be higher or lower in difference samples in a diseased skin.

Hence the rejection is maintained.

***Claim Rejections - 35 USC § 112- 1<sup>st</sup> paragraph***

In view of applicants argument, the rejection of claims 15-16 and 35-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, has been **withdrawn**.

In view of applicants argument, the rejection of claims 15-16 and 35-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been **withdrawn**.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-16, 35-36, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable Bickers et al., Janmohamed et al., Nelson et al., and Rylander et al.

Claims 15-16 and 35 are drawn to a method of determining the effectiveness of a skin treatment, wherein upon administering said skin treatment, CYP2S1 level is increased or decreased. Claims 36 and 40-41 are drawn to a method of determining whether a subject is likely to respond to a skin treatment with a chemical that is metabolized by CYP2S1 by comparing the level of CYP2S1 in a first sample of a diseased skin and a second sample of a non-diseased skin from a subject.

Bickers et al. (*J Clin Invest* **62** (1978), p. 1061-1068 - form PTO-892) discloses a method of a method of detecting effectiveness of a skin treatment comprising of coal tar or whether a subject is likely to respond to a skin treatment comprising of coal tar by measuring the enzyme's level (page 1062). With this teaching at hand, one having ordinary skill in the art would have looked to other known cytochrome P450 enzymes shows genes have been cloned in order to better measure or detect cytochrome P450 enzyme in tissue.

The difference between the reference of Bickers et al. and the instant claims is that the reference of Bickers et al. does not disclose a method of using CYP2S1 as the cytochrome P450 enzyme.

Janmohamed et al. (*Biochem Pharmacol* 62 (2001), pp. 777–786 - form PTO-892) discloses the expression of members of the CYP 2 family in human skin (abstract, pages 778-781). Janmohamed et al. discloses that several mammalian CYP families have been identified and cites Nelson et al. (*Arch Biochem Biophys*. 1999 Sep 1;369(1):1-10 – form PTO-892) which discloses a UNIGENE of CYP2S1 (page 778 of Janmohamed et al. and page 2 of Nelson et al.). Rylander et al. (*Biochem Biophys Res Commun* 281 (2001), pp. 529–535 – form PTO-1449) discloses isolation and cloning of a CYP2S1, method of detecting CYP2S1 using an antibody and detecting CYP2S1 mRNA levels (pages 530, 532 and 533).

Therefore, combining the above references, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine which of the CYP proteins disclosed by Nelson et al. are expressed in human skin and (1) determine whether a subject is likely to respond to a skin treatment, such as coal tar, by comparing the level of a CYP, such as the CYP2S1 of Rylander et al., in a first sample of a diseased skin and a second sample of a non-diseased skin from a subject, and (2) determine the effectiveness of a skin treatment, such as coal tar, wherein upon administering said skin treatment, CYP, such as CYP2S1, level is increased or decreased.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the CYP protein used in Bickers et al. with other CYP proteins which have been cloned, such as the CYP2S1 enzyme of Rylander et al., allowing easier and more specific detection of CYP levels in tissue. One of ordinary skill



in the art at the time the invention was made would have had a reasonable expectation for success because Janmohamed et al. teaches expression of several CYP 2 family proteins in skin, Rylander et al. teaches the cDNA sequence encoding a CYP2S1 protein and how to detect the enzyme's level in tissue using antibodies or measuring CYP2S1 mRNA, and Northern blot analysis of the distribution of proteins in human tissue is well known and taught by Rylander et al and Janmohamed et al.

Therefore, Bickers et al., Janmohamed et al., Nelson et al., and Rylander et al. render claims 15-16, 35-36, and 40-41 *prima facie* obvious to those skilled in the art.

### **Conclusion**

Claims 15-16, 35-36, and 40-41 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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/Yong D Pak/  
Primary Examiner, Art Unit 1652